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Applicants : Nicole Suciu-Foca et al.
U.S. Serial No. : 09/746,311
Filing Date : December 21, 2000
For : GENERATION OF ANTIGEN SPECIFIC T
SUPPRESSOR CELLS FOR TREATMENT OF
REJECTION

1185 Avenue of the Americas
New York, New York 10036
August 9, 2002

Assistant Commissioner for Patents
Washington, D.C., 20231

Sir:

INFORMATION DISCLOSURE STATEMENT

Applicants submit herewith an Information Disclosure Statement under 37 C.F.R. §1.56.

In accordance with their duty of disclosure under 37 C.F.R. §1.56 and 37 C.F.R. §1.97, applicants would like to direct the Examiner's attention to the following publications which are listed on the attached Form PTO-1449 (**Exhibit A**). Copies of cited publications 3, 4, 6, 8, 9, 11, 18, 19, and 25 are attached hereto as **Exhibits 1-9**, respectively. Publications 1, 2, 5, 7, 10, 12-17, 20-24 and 26 are of record in prior application U.S. Serial No. 09/333,809, filed June 15, 1999, to which priority under 35 U.S.C. §120 is claimed. According to 37 C.F.R. §1.98(d), copies of patents or publications that are of record in such prior application need not accompany this Information Disclosure Statement.

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1. Banchereau, J. and R.M. Steinman. (1998) "Dendritic cells and the control of immunity". *Nature* 392:245-252.
2. Barker, T.D., et al. (1996) "Identification of multiple and distinct CD8⁺ T cell suppressor activities: dichotomy between infected and uninfected individuals, evolution with progression of disease, and sensitivity to gamma irradiation". *J. Immunol.* 156:4476-4483.
3. Batliwalla, F., et al. (1996) "Oligoclonality of CD8⁺ T cells in health and disease: aging, infection, or immune regulation?". *Hum Immunol.* 48:68-76. Review. (Exhibit 1).
4. Benichou, G. and E.V. Fedoseyeva. (1996) "The contribution of peptides to T cell allorecognition and allograft rejection". *Intern. Rev. Immunol.* 13:231-243. (Exhibit 2).
5. Bennett, S.R.M., et al. (1998) "Help for cytotoxic-T-cell responses is mediated by CD40 signaling". *Nature* 393:478-480.
6. Cella, M., et al. (1997) "A novel inhibitory receptor (ILT3) expressed on monocytes, macrophages, and dendritic cells involved in antigen processing". *J. Exp. Med.* 185:1743-1751. (Exhibit 3).
7. Ciubotariu R., et al. (1998) "Specific suppression of human CD4⁺ T helper cell responses to pig MHC antigens by CD8⁺CD28⁻ regulatory T cells". *J. Immunol.* 161:5193-

5202.

8. Colonna, M., et al. (1998) "Cutting edge: human myelomonocytic cells express an inhibitory receptor for classical and nonclassical MHC class I molecules". *J. Immunol.* 160:3096-3100. (**Exhibit 4**).
9. Colovai, A.I., et al. (2000) "Induction of xenoreactive CD4+ T-cell anergy by suppressor CD8+CD28- T cells". *Transplantation.* 69:1304-1310. (**Exhibit 5**).
10. Damle, N.K., et al. (1983) "Alloantigen-specific cytotoxic and suppressor T lymphocytes are derived from phenotypically distinct precursors". *J. Immunol.* 131:2296-2300.
11. Deeths, M.J., et al. (1999) "CD8+ T cells become nonresponsive (anergic) following activation in the presence of costimulation". *J Immunol.* 163:102-110. (**Exhibit 6**).
12. Groux, H., et al. (1997) "A CD4+ T-cell subset inhibits antigen-specific T-cell responses and prevents colitis". *Nature* 389:737-742.
13. Jiang, S., et al. (1998) "Induction of MHC-class I restricted human suppressor T cells by peptide priming in vitro". *Human Immunol.* 59:690-699.
14. Lanier, L.L., et al. (1995) "CD80 (B7) and CD86 (B70) provide similar costimulatory signals for T cell proliferation, cytokine production, and generation of

CTL". *J. Immunol.* 154:97-105.

15. Liu, Z., et al. (1998) "Specific suppression of T helper alloreactivity by allo-MHC class I-restricted CD8⁺CD28⁻ T cells". *Int. Immunol.* 10:775-783.
16. Lombardi, G., et al. (1994) "Anergic T cells as suppressor cells in vitro". *Science* 264:1587-1589.
17. Noble, A., Zhao, Z.S., and H. Cantor. (1998) "Suppression of immune responses by CD8 cells. II. Qa-1 on activated B cells stimulate CD8 cell suppression of T helper 2 responses". *J. Immunol.* 160:566-571.
18. Pantaleo, G., Demarest, J.F., Soudeyins, H., et al. (1994) "Major expansion of CD8⁺ T cells with a predominant V beta usage during the primary immune response to HIV." *Nature* 370(6489):463-467. (**Exhibit 7**).
19. Pennesi, P., Liu, Z., Ciubotariu, R., Colovai, A., Cortesini, R., and N. Suciu-Foca. (1999) "TCR repertoire of suppressor CD8⁺CD28⁻ T cell population". *Human Immunol.* 60:291-304. (**Exhibit 8**).
20. Qin, S., Cobbold, S.P., Pope, H., Elliott, J., Kioussis, D., Davies, J., and H. Waldmann. (1993) "'Infectious' transplantation tolerance". *Science* 259:974-977.
21. Ridge, J.P., Di Rosa, F., and P. Matzinger. (1998) "A conditioned dendritic cell can be a temporal bridge

between a CD4⁺ T-helper and a T-killer cell". *Nature* 393:474-478.

22. Schoenberger, S.P., Toes, R.E.M., van der Voort, E.I.H., Offringa, R., and C.J.M. Melief. (1998) "T-cell help for cytotoxic T lymphocytes is mediated by CD40-CD40L interactions". *Nature* 393:480-483.
23. Schwartz R.H. (1992) "Costimulation of T lymphocytes: the role of CD28, CTLA-4, and B7/BB1 in Interleukin-2 production and immunotherapy". *Cell* 71:1065-1068.
24. Tan, P., Anasetti, C., Hansen, J.A., Melrose, J., Brunvand, M., Bradshaw, J., Ledbetter, J.A. and P.S. Linsley. (1993) "Induction of alloantigen-specific hypo-responsiveness in human T lymphocytes by blocking interaction of CD28 with its natural ligand B7/F31". *J. Exp. Med.* 177:165-173.
25. Wells, A.D., Gudmundsdottir, H., and L.A. Turka. (1997) "Following the fate of individual T cells throughout activation and clonal expansion. Signals from T cell receptor and CD28 differentially regulate the induction and duration of a proliferative response". *J. Clin. Invest.* 100(12):3173-3183. (**Exhibit 9**).
26. Yang, Y., and J.M. Wilson. (1996) "CD40 ligand-dependent T cell activation: requirement of B7-CD28 signaling through CD40". *Science* 273:1862-1864.

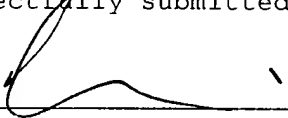
Each of the above-listed publications is listed again on the accompanying PTO Form-1449 (**Exhibit A**). Applicants request

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that the Examiner make the above-listed publications of record in the subject application.

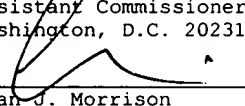
No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,


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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Assistant Commissioner for Patents
Washington, D.C. 20231


Alan J. Morrison
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Date